BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

REMARKS

Summary of the Office Action

In the Office Action, claims 1, 3-5, and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,454,788 to *Walker, et al.* ("*Walker*")

Claims 9-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Walker* in view of U.S. Patent No. 5,409,470 to *McIntyre, et al.*

Summary of the Response to the Office Action

Applicants propose canceling claims 4-12, without prejudice or disclaimer, adding claim 13, and amending claims 1 and 3. Accordingly, claims 1, 3, and 13 are pending for further consideration.

All Claims are Allowable

In the present invention, upon concurrently inserting the guide wire and the balloon catheter, until the guide wire reaches an entrance of the coronary artery, the guide wire is subjected to a minimum pressure drag from the blood stream. In the meanwhile, the guide wire is subjected to an increased pressure draft from the blood stream once it enters into the coronary artery. Thus, the forward propelling force is reinforced to readily make the guide wire insertable into a stenosis area (occluded area) in the deep and tortuous thin blood vessels.

Because the guide wire moves forward against the blood streams from the aorta through the aorta arch to the entrance of the coronary artery, the following advantages are obtained. The mirror-finished barrel portion is a stream-lined figure like a fusiform structure, the structure. Therefore, is likely subjected to a low drag from the blood streams due to its low drag coefficient

(Cd). The mirror-finished barrel portion reduces a friction drag against the blood stream so as to expel the thrombosis deposited thereon.

The front end of the balloon catheter is diametrically smaller than a maximum diameter of the mirror-finished barrel portion. Moreover, the front end of the balloon catheter elastically deforms to be diametrically greater than a tube portion of the balloon catheter so as to be a flared end portion when the mirror-finished barrel portion engages with the front end of the balloon catheter, in accompany with provisionally connecting the balloon catheter. Therefore, when the front end of the balloon catheter diametrically exceeds the maximum diameter of the mirror-finished barrel portion, an area increases in which the balloon catheter is subjected from the blood streams. When the front end of the balloon catheter is diametrically smaller than the maximum diameter of the mirror-finished barrel portion, the drag resistance to which the balloon catheter is subjected, is generally equal to the drag resistance to which the mirror-finished barrel portion is subjected from the blood stream.

Within the coronary artery, the balloon catheter moves forward together with the mirror-finished barrel portion in such a direction as the blood streams run. For this reason, the blood stream run in parallel along the outer surface of the tube portion of the balloon catheter. The blood stream disperses at the flared end portion of the balloon catheter to give a reaction force to the flared end portion so as to help propel the balloon catheter forward.

Because the tube portion of the balloon catheter is not mirror-finished, the drag resistance increases between the tube portion and the blood stream. This also adds a reaction force to the balloon catheter to help it propel forward.

With the mirror-finished barrel portion covered by the flared end portion, the non-mirror-finished tube portion of the balloon catheter increases the friction drag. With the increased friction drag, the flared end portion increases the pressure drag to readily make the balloon catheter deeply insertable into the blood vessel together with the mirror-finished barrel portion.

The provisionally connecting means between the mirror-finished barrel portion and the tube portion of the balloon catheter, increases the drag coefficient. This is illustrated on page 5, lines 9-15 of the subject specification. which describes the "common synthetic resin combination" and the "great enough coefficient of the static friction."

The reason why the mirror-finish barrel portion is conceived is to realize the provisionally connecting means which performs a tight engagement against the balloon catheter, as illustrated on page 14, line 23 to page 15, line 1.

In general, the method of manufacturing the balloon tube is by means of an extrusion process with the use of metallic mold such as a dice, a nipple or the like. For this reason, an inner surface of the metallic mold is as smooth as a mirror-finished surface. The subject concept is to make the mirror-finished surface of the barrel portion engage with the inner smooth surface of the balloon tube so as to increase the drag coefficient (Cd), thus producing the physical absorption in the provisionally connecting means. Namely, the subject concept is that the provisionally connecting means makes it easier to perform the connection and detachment between the mirror-finished barrel portion and the balloon tube.

An engagement force of the provisionally connecting means has the following factors. First is the physical absorption between the mirror-finished surface of the barrel portion and the inner smooth surface of the balloon tube. Second is a mechanical engagement produced as a

contraction force reactive to an expansible force of the front end tube of the balloon catheter. Third is an attachment action produced with the blood stream direction taken into consideration, which is an auxiliary attachment force produced by rotational flows reversal to the blood stream direction kept until reaching the entrance of the coronary artery. Within the coronary artery, another attachment action applied by pushing the flared front end due to the blood streams.

The detachment force is produced by considering it as an opposite action of the above-mentioned item. When the barrel portion is entirely covered by the front end tube of the balloon catheter, it becomes difficult to detach the barrel portion from the front end tube of the balloon catheter. In particular, the very thin wire is used for the guide wire (helical spring) to make it highly flexible with less rigidity. This readily makes the very thin wire deform (buckle) within the front end tube, thus making it more difficult to detach the guide wire from the barrel portion. This is true with the case when the front end tube of the balloon catheter covers more than half of the barrel portion extending beyond its maximum diameter section.

Regarding the soldering portion fixedly provided on the helical spring to produce the mirror-finished barrel portion, due to the soldering portion fixedly securing the helical line elements to the elongation core, these three sections are strongly connected to form the solidly integrated barrel portion structure. The barrel portion can be secured at any place desired, regardless of the length and position of the helical coil spring. With the use of silver or gold solder as radiopaque material, it functions as a marker.

Another reason why the solder-formed barrel portion is mirror-finished is as below. The mirror-finished treatment is provided on the barrel portion to decrease its contact angle against

the liquid phase because the soldering metal has a low wettability. The mirror-finished treatment decreases a surface tension energy to suppress the thrombosis formation and deposit.

Claim 13 represents the provisionally connecting means in which both lengthwise sides of the mirror-finished barrel portion form parallel flat sections. This notion includes the physical absorption by the mirror-finish surface and a mechanical engagement attachment. The latter mechanical engagement attachment becomes stronger in the mirror-finished barrel portion at its outer surface than the one circular in cross section. This is because the circumferential length becomes greater to increase the mechanical engagement attachment when the cross sectional area of both the former and latter is the same.

Moreover, upon connecting the mirror-finished barrel portion and the front end tube of the balloon catheter, the mirror-finished barrel portion imparts a high stress to the front end tube at cornered points. The front end tube is bent at the cornered points, and forcibly deformed in a tensile direction to enhance a contraction force.

Walker fails to teach or suggest the claimed features of claims 1, 3 and 13 as described above. In every embodiment of U.S.P. 5,454,788 (*Walker*), a cavity is formed where the resilient sleeve 41 is brought into its engagement with the cylindrical collar 46. This exposes the sleeve 41 to a greater pressure drag until reaching the entrance of the coronary artery. Even after entering the coronary artery, reverse rotational flows are induced in the direction opposite to the blood streams so as to block the forward movement of the catheter. Thus, Walker does not teach or suggest a technological breakthrough that makes use of the blood streams on the strength of the structural characteristics.

The surface of the cylindrical collar 46 of *Walker* is polished to enhance the smoothness to easily slip the cylindrical collar 46 within the sleeve 41 (e.g., silicone and teflon coating). On the contrary, the subject invention intends to increase the draft coefficient (Cd) to realize the physical absorption through the engagement between the mirror-finished surface and the smooth surface of the front end tube of the balloon catheter. The subject invention intends to secure an easy connection and ready detachment through the physical absorption by means of the provisionally connecting means, thus structurally distinguishing the subject invention from the *Walker* invention.

The cylindrical collar 46 of *Walker* has no effect which the subject invention, as previously described. The subject invention needs no pierce hole like bead, and requires neither a ring marker nor an adhesive provided on the mirror-finished barrel portion. The mirror-finished barrel portion can be soldered at any place as desired due to the structure in which the mirror-finished barrel portion is formed by providing soldering portion fixedly on the helical spring portion.

MPEP § 2131 states that a claim is anticipated only if each and every element as set forth in the claim is found in a single reference. As noted above, *Walker* fails to teach every feature of the claimed invention as recited in independent claim 1. In view of the above arguments, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 102(b) be withdrawn. Additionally, claim 13 which now depends from independent claim 1, is allowable at least because its base claim is allowable, as well as for the additional features recited therein.

Rejection Under 35 U. S.C. § 103(a)—Walker in view of McIntyre

Claims 9-12 stand rejected under 35 U.S.C § 103(a) as allegedly being unpatentable over *Walker* in view of U.S. Patent No. 5,409,470 to *McIntyre et al.* ("*McIntyre*"). Applicants respectfully submit that the rejection is moot because of the above-mentioned cancellation of claims 4-12.

CONCLUSION

In view of the foregoing, Applicants respectfully request the entry of this Amendment to place the application in clear condition for allowance or, in the alternative, in better form for appeal. Applicants also request the Examiner's reconsideration and reexamination of the application and the timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

By: Mary Jane Boswell
Mary Jane Boswell
Reg. No. 33,652

Dated: March 22, 2004

Customer No. 009629
CUSTOMER NO. 09629
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Telephone: (202) 739-3000
Facsimile: (202) 739-3001